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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,218	09/08/2003	Ernst Peter Strecker	12013/56004	1060

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EXAMINER	
WILLSE, DAVID H	

ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,218	STRECKER, ERNST PETER	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-36 and 38-51* is/are pending in the application.

4a) Of the above claim(s) *39-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36, 38, and 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election of Species II in the reply filed on November 16, 2006, is acknowledged. Because the Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The Applicant asserts that claims 38-51 are generic. (The examiner assumes that the Applicant intended to state that claims 39-48 are generic, because claims 38 and 49-51 depend from claim 33 or 36.) On page 10 in the reply of July 27, 2006, the Applicant relies upon the embodiments shown in Figures 5-6 for overcoming the rejections under 35 U.S.C. 112 as set forth in the Office action of January 11, 2006. If one of the pairs of "first opening size" and "second opening size" (claim 39, last two lines) can be broadly interpreted as being not necessarily the same as (or equal to) another pair of first and second opening sizes (of one of the three fluid orifices), then the examiner agrees with the Applicant. However, there is no suggestion of combining the wrinkled embodiment with either prosthesis shown in Figures 5-6 and certainly no explanation to the ordinary practitioner as to how a wrinkled lining would be applied to cover the structure surrounding the branching orifice (US 6,193,746 B1: column 4, lines 36-38, for example) so as to enable the orifice to expand sufficiently and in such a way that neither the structure nor the wrinkled material impedes blood flow. Claims 39-48 are thus withdrawn as being directed to a non-elected species.

The examiner has withdrawn the rejection of claims 33-38 under 35 U.S.C. 112, first paragraph, because although the original disclosure does not explicitly state that the wrinkled species can possess a continuous and connected lining (claim 33, line 8), an inner lining portion (claim 34), and so on, such features would have been inferred by one of ordinary skill to be within the realm of disclosed variants in view of column 2, lines 29-32 (which suggests pores

and/or biodegradable materials); column 3, lines 51-62 (which suggests a continuous and connected lining and/or an inner lining for the medication impregnated wrinkled lining); and column 3, lines 63-67 (which suggests a lining with several layers for said wrinkled lining); along with the Applicant's citations (which explicitly describe these claim limitations).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-36, 38, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz, US 5,957,971. The embodiment shown in Figure 2 includes an elongated hollow structure **34** and a wrinkled lining **32** interfaced with a medication for delivery to a patient (column 5, lines 31-40; column 2, lines 24-27; column 4, line 30 et seq.). The wrinkled lining **32** extending to the ends of the structure **34** would have been an obvious variant in order to better distribute the drugs along the stent, with further motivation having been provided by the fibrin coating **24** extending from end to end in the Figure 1 embodiment. Regarding claim 34 and others, the lining is positioned *within* the structure in the sense that it lies *between* successive

helical coils of the stent **34** (Figures 2 and 10). Regarding claim 35: column 2, lines 28-29; column 6, lines 46-48; etc. Regarding claims 36 and 49: column 3, lines 40-43 and 65-67; different medications would have been obvious to the ordinary practitioner from the drugs listed (column 2, lines 9-11 and 29-33; column 4, lines 15-17 and 45-47; column 6, line 33; etc.) in order to impart multiple effects as indicated for a particular patient. Regarding claims 38 and 50, pores would have been inherent from the incorporation of controlled-rate microcapsules (column 4, lines 48-55).

The Applicant's remarks have been reviewed. The "different medications" (instant claim 36, last line) could be two medications that are different from each other and both present in the two or more layers. Moreover, each layer consisting of only one medication different from that of other layers would have been obvious in order to provide different drug release rates. The Applicant's assertion that "the fibrin film 32 does not include medication" (page 11, lines 18-19) is not understood, and the Applicant does not address the above citations which clearly demonstrate the presence of drug delivery in embodiments of the Schwarz stent.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dave Willse
Primary Examiner
Art Unit 3738